

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration New England District

> Food and Drug Administration One Montvale Avenue Stoneham, Massachusetts 02180 617)279-1675 FAX: (617)279-1742

HFI-35

## WARNING LETTER

October 16, 1997

NWE-02-98W

## VIA CERTIFIED MAIL RETURN RECEIPT REQUESTED

Charles I. Hanna, President Cedar's Mediterranean Foods, Inc. 132 Plaistow Road P.O. Box 1037 Plaistow, NH 03865

Dear Mr. Hanna:

During an inspection of your firm, Investigator Geraci collected samples of three (3) products labeled "Cedars, Naturally Delicious", specifically: 1) Garlic Lovers Hommus Tahini, 2) Garlic and Chive Hommus Tahini, and 3) Beantown Sports Dip.

Our review of the labels for these products reveals that they cause the products to be in violation of Section 403 of the Food, Drug and Cosmetic Act as follows:

Garlic Lovers Hommus Tahini - Sample #97-749-452 and Roast Garlic and Chive Hommus Tahini- Sample #97-749-454

The above products are misbranded within the meaning of Section 403 (i) (2) of the Act, in that they are fabricated from two or more ingredients, but their labels fail to bear the common or usual name of each ingredient. Laboratory analyses found the products to contain sodium benzoate; however,, sodium benzoate is not declared in the list of ingredients as required by Title 21, Code of Federal Regulations (21 CFR) 101.4. These products are also misbranded within the meaning of 403 (k) of the Act, in that they contain a chemical preservative but the labels fail to state that fact.

## Beantown Sports Dip - Sample #97-749-455

The above product is misbranded within the meaning of Section 403 (i) (2) of the Act, in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient. Laboratory analyses found the product to contain sodium benzoate; however, sodium benzoate is not declared in the list of ingredients as required by 21 CFR 101.4. The product is also misbranded within the meaning of Section 403 (k) of the Act, in that the product contains a chemical preservative, but the label fails to state that fact.

The above product is misbranded within the meaning of Section 403 (r) (2) (b) of the Act, in that the label bears the terms "saturated fat free" and "cholesterol free", but fails to bear the required referral statement (21 CFR 101.13 (g) (2)).

The above product is misbranded within the meaning of Section 403 (r) (1) (A) of the Act, in that it bears the nutrient content claim "protein packed", which has not been authorized for use by FDA.

The above product is misbranded within the meaning of Section 403 (e) (1) of the Act, in that the label does not bear a name of a manufacturer, packer or distributor.

The above violations concern certain labeling requirements and are not meant to be an all inclusive list of deficiencies on your labels. Other label violations can subject the food to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should take prompt action to correct these label deficiencies. Failure to promptly correct these label deficiencies may result in regulatory action being initiated by FDA without further notice. These include seizure and injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason, and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, New England District Office, Attention: E. Frank Gesing, Compliance Officer, One Montvale Avenue, Stoneham, MA 02180.

Sincerely yours,

John R. Marzilli

District Director

New England District Office